

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

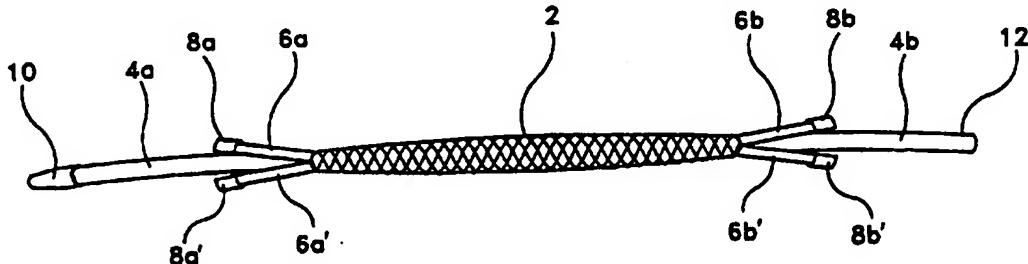


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ :	A1	(11) International Publication Number: WO 96/22745
A61F 2/06		(43) International Publication Date: 1 August 1996 (01.08.96)

(21) International Application Number: PCT/US96/00397	(81) Designated States: CA, DE, JP, MX, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 16 January 1996 (16.01.96)	
(30) Priority Data: 08/377,069 23 January 1995 (23.01.95) US	Published <i>With international search report.</i>
(71) Applicants: SCHNEIDER (USA) INC. [US/US]; 5905 Nathan Lane, Plymouth, MN 55442 (US). INDIANA UNIVERSITY FOUNDATION [US/US]; Indiana University Hospital, 550 North University Boulevard, Indianapolis, IN 46202 (US). JOHNS HOPKINS UNIVERSITY [US/US]; 3400 North Charles Street, Baltimore, MD 21218 (US).	
(72) Inventors: TREROTOLA, Scott, O.; 1196 Helford Lane, Carmel, IN 46032 (US). JOHNSON, Wade, M.; 4749 - 12th Avenue South, Minneapolis, MN 55407 (US).	
(74) Agent: NIKOLAI, Thomas, J.; Haugen and Nikolai, P.A., Suite 820, 900 Second Avenue South, Minneapolis, MN 55402-3325 (US).	

(54) Title: PERCUTANEOUS STENT-GRAFT AND METHOD FOR DELIVERY THEREOF



(57) Abstract

A percutaneous stent graft is disclosed for restoring blood flow between vessels. The stent graft has a body implantable device (2) and first and second retaining elements (4a, 4b). Also disclosed are methods for deploying a stent graft.

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
Cs	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

PERCUTANEOUS STENT-GRAFT AND
METHOD FOR DELIVERY THEREOF
Background of the Invention

Over 130,000 patients undergo chronic hemodialysis in the 5 United States each year. Access to the blood supply is generally sought through vasculature, but such access may eventually fail due to the formation of scar tissue inside the vessel or due to vessel occlusion. Failure of hemodialysis access contributes to morbidity, hospitalization time, and the 10 cost of treatment.

It is known in the art to regain vessel access with new hemodialysis grafts and hemodialysis graft revisions which are performed surgically. The Brescia-Cimino direct radiocephalic fistula is a preferred form of permanent access, but access is 15 generally regained by implanting bridge grafts. The majority of such grafts in the United States are made of synthetic graft material such as PTFE. Unfortunately, PTFE bridge grafts are much more prone to stenosis and thrombosis than the natural vessels.

20 While percutaneous interventional techniques (such as thrombolysis, angioplasty, atherectomy, and stent placement) are becoming increasingly popular in the management of hemodialysis access graft complications, these techniques generally eventually fail, necessitating surgical revision. 25 Such revision usually consists of the implanting of a PTFE interposition graft, and offer 30-day patencies of about 44-65%. Occasionally, the interposition grafts do not fully span the diseased segment due to lack of imaging guidance. Surgical revision of these lesions may entail patch angioplasty or 30 placement of an interposition graft.

PTFE interposition grafts are also often placed in patients who have a failed native fistula. Usually, these fistulae retain a small segment of patent vein beyond the anastomosis, and have reconstitution of veins further up the 35 arm via collaterals. This segment of vein is used to form an arterial anastomosis of the interposition graft.

The advent of covered stents and stent-grafts has made possible the revascularization of long segment occlusion in the arterial system. To date, however, such grafts have been used 40 intravascularly. In other words, the grafts have been inserted

-2-

inside of natural veins or arteries. The ends of these grafts are generally held in place by stents which are either attached to or incorporated into the graft itself, creating "sutureless anastomoses".

5 It is an object of the present invention to provide extravascular revision and *de novo* creation of arteriovenous shunts for hemodialysis and other applications. In particular, it is an object of the present invention to provide a percutaneous stent-graft and a method for delivery thereof to 10 provide increased vascular flow in patients requiring the same.

It is a further object of the present invention to provide methods for using percutaneous stent-grafts in a variety of medical applications, such as femoropoplital, femorals, iliacs, femoral-femoral, brachial-axillary, and 15 forearm loops. These applications include arterial-arterial, venous-venous, arterio-venous, and graft to vessel applications.

Summary of the Invention

These and other objects are achieved by the apparatus and 20 methods of the present invention. The present invention relates to percutaneous creation of "anastomoses" and the performance thereof in an extraanatomic fashion to create an arteriovenous shunt. The technique is relatively simple and effective. Preferred use of peel-away sheaths circumvents a 25 problem with the insertion of extraanatomic grafts; namely one has to "give up" both ends of the device at some point, so over-the-wire insertion is not possible. Tandem peel-away sheaths represent a simple, effective means of insertion of both ends of the graft into their respective vessels.

30 In sum, the present invention relates to an apparatus for providing access to a blood supply. The apparatus has a body implantable device made of a flexible tube of open weave construction having a first end and a second end, the ends being compressible into radially compressed states, the 35 flexible tube having an elastic layer arranged along at least a portion of its length, and first and second removable retaining elements secured to the flexible tube proximate the first and second ends, respectively, for maintaining the first and second ends in radially compressed states, the retaining elements 40 being adapted for insertion into vascular access means. The

removable retaining elements may be peel-away sheaths, which may be a tubular material attached to at least two leaves, the leaves upon an application of force being adapted to tear the tubular material thereby separating the sheath into removable 5 pieces. The leaves may have handles to facilitate the application of the force. The flexible tube may be constructed of helical, braided strands of biocompatible material, such as stainless steel, Elgiloy, Nitinol, combinations thereof, or plastic. The elastic layer may cover at least part of the 10 internal or external surface of the flexible tube, or the elastic layer may at least partially embed the flexible tube. The elastic layer may be a semi-permeable biostable material such as polytetrafluoroethylene, polyester, polyurethane, or silicone. The flexible tube may be self-expanding, and the 15 ends may be elastically compressible.

The present invention also relates to a system for delivering a percutaneous stent-graft. The system includes a) a body implantable device made of a flexible tube member of open weave construction having a first end and a second end, 20 the ends being compressible into radially compressed states, the flexible tube having an elastic layer disposed along at least a portion of its length; b) first and second removable retaining elements secured to the flexible tube proximate the first and second ends, respectively, for maintaining the first 25 and second ends in radially compressed states wherein the retaining elements are adapted for insertion into vascular access means; and c) first and second vascular access means adapted to receive the first and second removable retaining elements, respectively.

30 The present invention also relates to a method for delivering a percutaneous stent graft to a patient. The method includes a) creating two incisions and tunneling between the two incisions below skin level to create a percutaneous, extravascular lumen; b) inserting a stent graft into the 35 percutaneous, extravascular lumen, wherein the stent graft has a first end and a second end, the first end being placed into one of the incisions and the stent graft being pushed until it is disposed in large part within the percutaneous, extravascular lumen, and c) inserting the first end of the 40 stent-graft into a first vascular segment and the second end of

-4-

the stent graft into a second vascular segment to create a percutaneous, extravascular lumen for allowing blood flow.

The present invention also relates to a method for delivering a percutaneous stent-graft to a patient including a) 5 inserting a first vascular access means into a first body lumen section of the patient; b) inserting a second vascular access means into a second body lumen section of the patient; c) providing an apparatus having body implantable device made of a self-expanding flexible tube of open weave construction having 10 a first end and a second end, the ends being compressible into a radially compressed state, the flexible tube having an elastic layer arranged along at least a portion of its length, first and second removable retaining elements secured to the flexible tube proximate the first and second ends, 15 respectively, for maintaining the first and second ends in radially compressed states, the retaining elements being adapted for insertion into the first and second vascular access means; d) inserting the first and second removable retaining elements into the first and second vascular access means, 20 respectively; e) pushing the first and second removable retaining elements into the first and second vascular access means, respectively, until at least part of the flexible tube first end is disposed within the first body lumen and at least part of the flexible tube second end is disposed within the 25 second body lumen; f) removing the first and second vascular access means; and g) removing the first and second retaining means thereby allowing the first and second end sections to expand within the first and second body lumen sections, respectively. The method may further include the step of 30 tunnelling between two incisions to create a percutaneous path for the stent-graft. The body implantable device may have at least one barb configured for engaging the internal surface of the first and second vessel segments.

Brief Description of the Drawings

35 The following figures have been provided to illustrate, but not limit, the present invention.

FIG. 1 is a side elevational view of the percutaneous stent-graft of the present invention;

FIG. 2 is a side elevational view showing a percutaneous 40 stent-graft of this invention with gripping means;

-5-

FIGS. 3(a)-3(c) are side elevational views showing peel-away sheaths of the present invention;

FIGS. 4(a)-4(i) illustrate a method for delivering a percutaneous stent-graft of the present invention;

5 FIGS. 5(a)-5(c) are side elevational views of three embodiments of the body implantable device of the present invention;

FIG. 6 is a side view of an anchoring means of the present invention;

10 FIGS. 7(a)-7(b) are side elevational views of alternative stent-grafts of the present invention;

FIG. 8 is a top view of an alternative stent-graft of the present invention; and

15 FIGS 9(a)-9(c) show three configurations of the stent-graft of the present invention inside human anatomy.

Description of the Preferred Embodiments

FIG. 1 illustrates a percutaneous stent-graft of the present invention. A body implantable device 2 consists of a stent-graft, in this case a self-expanding flexible tube member 20 of open weave construction covered by an elastic layer. In alternative embodiments, the tube member will not be self-expanding. On each end are removable retaining elements 4a,b. The flexible tube 2 lies in part within each removable retaining means 4a,b in a compressed state. When the retaining means 4a,b are removed in this embodiment, the flexible tube ends will self expand under an elastic restoring force. In alternative embodiments, the ends can be expanded by other means, such as by a balloon. The removable retaining means 4a,b in this case are peel-away sheaths having leaves 6 a,a',b,b' and handles 8 a,a',b,b'. A removable tip 10 is shown on one of two releasable retaining means. The tip 10 is capable of sealing-off blood flow through the stent-graft after end 12 is inserted, but tip 10 is removed prior to insertion into vascular access means 16. End 12 will generally be 35 configured for slidable insertion into vascular access means, as will be the end within tip 10.

The stent-graft of the present invention may include a flexible tube such as stents that are known in the art. See, for instance, United States Patent Nos. 4,655,771; 4,848,343; 40 4,850,999; 5,061,275; and 5,064,435. (All documents cited

herein, including the foregoing, are incorporated herein in their entireties for all purposes.) The stents will preferably be self-expanding, however balloon expandable stents may be used under certain circumstances.

5 The elastic layer will preferably cover the flexible tube at least in part, but it may also be configured inside of the flexible tube at least in part, or it may embed the filaments of the flexible tube at least in part. Elastic layers used in grafts and covered stents that are known in the art are 10 generally suitable for use in the present invention. Preferred elastic layers are made from PTFE or polyurethane. Alternatively, polyester weaves or silicone can be used. Silicone layers may be electrostatically spun.

FIG. 2 shows a percutaneous stent-graft of the present 15 invention with gripping means 14a,b. The gripping means 14a,b allow the stent-graft to be handled, and especially inserted into the vascular access means, without damaging the flexible tube member 2. In the embodiment shown, gripping means 14a,b is a peel-away sheath having leaves 16a,a',b,b' and handles 20 18a,a',b,b'. In this embodiment, two gripping means 14a,b are shown, each configured between exposed tube member 2 and removable retaining elements 4a,b. In other embodiments, there will be, for instance, a single gripping means 14 configured between removable retaining means 4a,b.

25 FIGS. 3(a)-3(c) show a method by which removable retaining element 4a,b, gripping means 14a,b, or vascular access means 26a,b can be removed. Reference is made in the figures to removable retaining elements 4a,b, but the principle is equally applicable to gripping means 14a,b or vascular 30 access means 26a,b. The leaves 6a,a' and handles 8a,a' will generally lie against the tubular outer surface of the retaining means 4a to maintain a low profile (FIG. 3a). In some cases, leaves 6a,a' will begin to open after ends 12 are inserted into vascular access means 26a,b (FIG. 3(b)). The 35 handles 8a,a' can be grabbed by finger tips or by a hemostat, and then pulled so that the handles 8a,a' and leaves 6a,a' are pulled from the tubular body of the retaining means (FIG. 3c). A continued pulling force can then be exerted against handles 8a,a' or leaves 6a,a' in generally opposite directions, creating 40 a tear along line 20. Continued pulling force will tear the

tubular body of the retaining means 4a along its entire length creating separated pieces, which can then be removed.

Alternative retaining elements that can be used pursuant to this invention include clasps that can be opened for 5 removal, or adhesive strips that can be separated for removal.

FIGS. 4(a)-4(i) illustrate a method for deploying the stent-graft of the present invention. Vascular access means 26a,b are inserted into a first vascular segment 22 and a second vascular segment 24, respectively (FIG. 4(a)). The 10 vascular access means 26a,b in this case are peel-away sheaths with leaves 38 a,a',b,b' and handles 30 a,a',b,b'. The distal ends of the vascular access means 26a,b are tubular and adapted to puncture the vascular segments to gain access thereto.

Incisions 32a,b are made to provide access for a tunneling 15 means 34 (4(b)). Vascular access means 26a,b are placed within the incision opening. Tunnel means 34, in this case a peel-away sheath/dilator system, is then pushed into one incision and out the other incision so that it is situated under the skin. A first retaining element 4a is inserted through 20 incision 32b into tunnel means 34 and pushed until first retaining element 4a exits incision 32a, at which point first retaining element 4a is inserted into the first vascular access means 26a (FIG. 4 (c)). As first retaining element 4a is pushed into first vascular access means 26a, leaves 6a,a' open 25 up to a partially open position. The peel-away tunnel 34 is removed by pulling leaves 36a,b, thereby tearing tunnel 34 along its entire length, and then removing the pieces. (FIG. 4(d)). First vascular access means 26a is then peeled-away while ensuring that first retaining element 4a means does not 30 materially alter its position (FIG. 4(e)). First retaining element 4a is then peeled-away, thereby deploying a first end 40 of the stent-graft into the first vessel segment 22 (FIG. 4(f)). The stent-graft is deployed in first vessel segment 22. (FIG. 4(g)). Second retaining element 4b is then inserted into 35 second vascular access means 26b (FIG. 4(h)). Second vascular access means 26b and then second retaining element 4b are then removed, deploying a second end 42 of the stent-graft in the second vessel segment 24 (FIG. 4(i)).

The peel-away sheaths of the present invention can 40 generally be removed by peeling and removing, or they may be

removed with a combined peeling/sliding action. For instance, retaining means 4a can be slid partially away from first vascular segment 22 while substantially maintaining the position of the stent graft 2; then retaining means 4a can be 5 partially peeled; then retaining means 4a can be slid further from the first vascular segment 22; then retaining means 4a can be further peeled, etc, until retaining means 4a separates and is then removed. Similar sliding/peeling methods of removal can be used with the gripping means 14, vascular access means 10 26, and tunnel means 34.

Removable retaining element 4, vascular access means 26, gripping means 14, and tunnel means 34 will be made from suitable materials, generally polymeric materials such as PTFE, FEP or polyethylene.

15 FIGS. 5(a)-5(c) illustrate alternative embodiments of the stent-graft of the present invention. In some cases the outer elastic layer will extend along the entire length of the wire mesh (not shown). It is preferable, however, to configure the stent graft so that it becomes anchored or fixed at each end 20 inside of the vessel segments in which it is inserted. Thus, FIG. 5(a) illustrates an embodiment where the outer flexible layer does not extend the full length of the wire mesh, creating a covered segment 44 and an uncovered segment 46 to the right of the dashed line which is exposed and more capable 25 of "grabbing" the inside of the vascular lumen. In FIGS. 5(b) and 5(c) the ends of the wire mesh filaments are configured with barbs 48 to grab onto the inside of the vascular lumen. An alternative barb 48' is illustrated in FIG. 6. Such 30 configurations enable the stent-graft to create a suitable seal with the inside of the vascular lumen, avoiding the need for sutures. In certain applications, however, sutures may be used to create a firmer seal.

FIGS. 7(a) and 7(b) show alternative stent-grafts of the present invention. FIG. 7(a) shows a first stent 48 and a 35 second stent 50, separated by a tubular elastic layer 52. The elastic layer has a first end 54 and a second end 56, each configured along the length of the respective stent. The stents 48,50 are attached to the elastic layer 52 by sutures 60. It is preferable for elastic layer 52 to at least 40 partially cover stents 48,50, but in certain embodiments it

-9-

will be configured so that the elastic layer 52 abuts the ends of the stents 48, 50, and the elastic layer is attached to the stents by some means such as by sutures. FIG. 7(b) shows an embodiment wherein elastic layer 52 embeds the filaments making up segments of the first stent 48 and the second stent 50. Sutures are not required in this particular embodiment.

FIG. 8 shows a top view of a stent graft of the present invention. In this embodiment, elastic layer 52 is configured outside of the filaments 58 making up the stents. In other 10 embodiments, the elastic layer will be configured inside of the filaments, or will embed the filaments.

FIGS. 9(a)-9(c) illustrate the present invention after stent-graft deployment in the body. FIG. 7(a) shows stent-graft revision of a brachial artery-axillary vein. FIG. 9(b) 15 shows stent-grafting of an arteriovenous forearm loop. FIG. 9(c) shows stent-grafting of an occluded femoral artery.

Example

20 An acute, non survival study was performed utilizing 10 adult mongrel dogs. All procedures were performed under general anesthesia (pentobarbital, titrated to effect). The animals were incubated and mechanically ventilated. For diagnostic arteriographic purposes, a 6 French sheath was 25 placed in the left carotid artery by cutdown. In all but 1 dog, both groins were shaved. In the remaining dog the right neck was shaved. No anticoagulants were given.

A) Device

In all but 1 animal, 6 millimeter diameter silicone 30 covered Wallstents were used ranging in length from 12 to 18 centimeters. In 1 animal, an 8 millimeter diameter silicone covered Wallstent was used. The stent-grafts were made by Schneider (USA) Inc, Minneapolis, MN. The stent-grafts were constrained at either end by a segment of 8 French peel-away 35 sheath.

B) Procedure

In 1 animal a straight 8 millimeter graft was created semipercutaneously between the right common carotid artery and right external jugular vein. The right common 40 carotid artery was exposed by cutdown and accessed with a

-10-

micropuncture set (Cook, Inc., Bloomington, IN). After exchanging for a .035 inch wire, the arteriotomy was dilated to 10 French and a 10 French peel-away sheath (B. Braun Medical Inc., Bethlehem, PA) was inserted. Next, percutaneous puncture 5 of the right external jugular vein was performed in a retrograde fashion using the micropuncture set. This access was also dilated to 10 French over a .035 inch wire. A 10 French peel-away sheath was inserted. Next, the dilator of the arterial peel-away sheath was removed and the arterial end of 10 the graft (enclosed in its own segment of peel-away sheath) passed through the sheath. The outer peel-away sheath was then removed followed by the inner peel-away sheath which resulted in deployment of the stent-graft within the vessel. Hemostasis was maintained by pinching the graft. Next, the venous end of 15 the graft (enclosed in its segment of peel-away sheath) was passed through the venous sheath and deployed in similar fashion to the arterial end of the graft. After placement of the second "anastomosis", arteriography was performed to demonstrate patency of the shunt.

20 The remaining 10 grafts in nine animals were placed in femoral loop fashion from the common femoral artery to the common femoral vein. For this procedure, a dermatotomy or short skin incision ranging from .5 to 4 centimeters was made just below the inguinal ligament. The vessels were not 25 dissected free. This incision only served to enable creation of a subcutaneous pocket and to make insertion of the ends of the stent graft through the peel-away sheaths easier. A 5 mm counterincision was made approximately 8 centimeters distal to the original incision. Using a hemostat, the pocket for the 30 femoral loop was created by blunt dissection from the counterincision toward the femoral incision/dermatotomy. A short (30 mm) .035 inch guide wire was pulled through each limb of the loop and left in place. Next, access was gained to the right common femoral artery and vein using a micropuncture set.

35 After exchanging for a .035 inch guide wire, the arteriotomy and venotomy were dilated and 10 French peel-away sheaths inserted. Next, an 18 French peel-away sheath was placed over each guide wire within the subcutaneous pocket and a 6 millimeter in diameter, 12-18 centimeter stent-graft was passed 40 through each peel-away sheath in order to form a femoral loop

-11-

(the length of the graft used was based on the available devices, the tunnel length was adjusted accordingly). A cap was placed on the venous end of the graft to promote hemostasis during graft insertion. Once the graft was in place in the 5 tunnel, the arterial end of the graft was placed through the 10 French peel-away sheath into the common femoral artery. The outer peel-away sheath was removed followed by the retaining peel-away sheath on the graft which resulted in deployment of the arterial end of the graft. Next, the venous end of the 10 graft was pinched to promote hemostasis and the cap removed. It was then placed through the venous sheath and deployed in similar fashion to the arterial end. One modification of this technique that was found helpful was to have a 5 French Fogarty catheter in the right external iliac artery which was inflated 15 just prior to placement of the graft and kept inflated during the 1 to 2 minutes that it took to deploy the graft. It was then deflated. This technique resulted in significantly better hemostasis, but it is not necessary.

After placement of the venous end of the graft, it 20 was palpated to confirm the presence of a thrill.

Arteriography was then performed using a catheter placed via the left carotid sheath into the ipsilateral external iliac artery. Arteriography was recorded using cut film or 105 millimeter spot film technique.

25 The animals were then kept alive but under anesthesia for up to 6 1/2 hours (range 1-6.5 hours, mean 4.1 hours). At the end of this time, repeat arteriography was performed to confirm continued patency of the graft. Repeat palpation was also performed. No anticoagulants were given 30 during this time or during any other portion of the procedure. In 2 animals, the procedure was carried out under sterile technique in anticipation of a survival experiment. The graft placement procedure was identical to that in the acute animals.

At the completion of the experiment, the animals 35 were killed with an overdose of pentobarbital. The stents were excised and examined grossly for any evidence of thrombosis or any other abnormality.

C) Results

10 successful percutaneous shunt placements and 1 40 semipercutaneous placement were achieved. All femoral loop

-12-

grafts developed a palpable thrill immediately after creation which was maintained for the duration of the experiment. The neck graft (our first graft) initially had a small amount of thrombus within it which was dislodged with a catheter via the 5 femoral approach. After dislodgement of this clot there was a palpable thrill in the graft. None of the femoral grafts developed thrombus at any time during the procedure; this was confirmed by visual inspection after graft removal. No "anastomotic" leaks were observed at any time during the 10 experiment. Small leaks in the silicone coating occurred in four grafts, in three of these hemostasis was achieved with gentle pressure. In one graft, continued leaking resulted in development of a hematoma and graft dislodgement at 1 hour post placement. None of the leaks were visible angiographically. 15 Fistulography in the femoral loops demonstrated widely patent grafts immediately after placement and just prior to sacrifice at 2.5-6.5 hours post placement; in three grafts delayed fistulography was not performed due to premature dislodgement. The single neck graft fistulogram initially showed some clot 20 but after clot dislodgement was widely patent and remained patent at 2 hours post placement (just prior to sacrifice).

Both attempted survival experiments were unsuccessful due to shunt dislodgement. Prior to attempting survival experiments, the hindlimbs of the acute animals had 25 been extensively manipulated showing good stability of the shunts; therefore it was felt that dislodgement would not occur in a conscious animal. However, in one animal, 1.5 hours after creation of the shunt, a large hematoma developed in the groin containing the shunt while lifting the dog to transfer it to 30 its cage. The shunt was confirmed fluoroscopically to be dislodged and the animal sacrificed. The second animal was transferred to its cage without lifting by the legs; however, as the animal awoke from anesthesia, repeated kicking apparently dislodged the shunt (3.5 hours after insertion) and 35 the animal developed a large hematoma in the groin. The shunt was confirmed fluoroscopically to be dislodged and the animal sacrificed.

One skilled in the art will appreciate that the foregoing figures, embodiments, and example are presented for purposes of 40 illustration and not for limitation. Alternative embodiments

-13-

will become apparent to one skilled in the art. For instance, the stent-graft of the present invention may have two biaxially configured stents sandwiching an elastic layer. Three stents may be used in various configurations. These and other 5 variations are within the purview of the present invention.

Claims

- 1) An apparatus for providing access to a blood supply, the apparatus comprising:
 - a body implantable device comprising a flexible tube of open weave construction having a first end and a second end, the ends being compressible into radially compressed states, the flexible tube having an elastic layer arranged along at least a portion of its length; and
 - first and second removable retaining elements secured to the flexible tube proximate the first and second ends, respectively, for maintaining the first and second ends in radially compressed states, the retaining elements being adapted for insertion into vascular access means.
- 2) The apparatus of claim 1, wherein the removable retaining elements comprise peel-away sheaths.
- 3) The apparatus of claim 2, wherein the peel-away sheaths comprise a tubular material attached to at least two leaves, the leaves upon an application of force being adapted to tear the tubular material thereby separating the sheath into removable pieces.
- 4) The apparatus of claim 3 wherein the leaves comprise handles to facilitate the application of the force.
- 5) The apparatus of claim 1 wherein the flexible tube is constructed of helical, braided strands of biocompatible material.
- 6) The device of claim 5 wherein the biocompatible material is selected from the group consisting of stainless steel, Elgiloy, Nitinol, and combinations thereof.
- 7) The device of claim 5 wherein the biocompatible material is a plastic.
- 8) The apparatus of claim 1 wherein the flexible tube has an internal surface and an external surface, and the elastic layer covers at least part of the external surface of the flexible tube.
- 35 9) The apparatus of claim 1 wherein the flexible tube has an internal surface and an external surface, and the elastic layer covers at least part of the internal surface of the flexible tube.
- 10) The apparatus of claim 1 wherein the elastic layer 40 at least partially embeds the flexible tube.

-15-

11) The apparatus of claim 1 wherein the elastic layer comprises a semi-permeable biostable material selected from the group consisting of polytetrafluoroethylene, polyester, polyurethane, and silicone.

5 12) The apparatus of claim 1, wherein the flexible tube is self-expanding, and the ends are elastically compressible.

13) A system for delivering a percutaneous stent-graft, the system comprising:

10 a body implantable device comprising a flexible tube member of open weave construction having a first end and a second end, the ends being compressible into radially compressed states, the flexible tube having an elastic layer disposed along at least a portion of its length;

15 b) first and second removable retaining elements secured to the flexible tube proximate the first and second ends, respectively, for maintaining the first and second ends in radially compressed states wherein the retaining elements are adapted for insertion into vascular access means; and

20 c) first and second vascular access means adapted to receive the first and second removable retaining elements, respectively.

14) The system of claim 13 wherein the first and second vascular access means comprise peel-away sheaths.

25 15) The system of claim 14 wherein the peel-away sheaths comprise a tubular material attached to at least two leaves, the leaves upon an application of force being adapted to tear the tubular material thereby separating the sheath into removable pieces.

30 16) The system of claim 15 wherein the leaves comprise handles to facilitate the application of the force.

17) A method for delivering a percutaneous stent graft to a patient, the method comprising:

35 a) creating two incisions and tunneling between the two incisions below skin level to create a percutaneous, extravascular lumen;

40 b) inserting a stent graft into the percutaneous, extravascular lumen, wherein the stent graft has a first end and a second end, the first end being placed into one of the incisions and the stent graft being pushed until it is disposed in large part within the percutaneous,

extravascular lumen, and

5 c) inserting the first end of the stent-graft into a first vascular segment and the second end of the stent graft into a second vascular segment to create a percutaneous, 5 extravascular lumen for allowing blood flow.

18) A method for delivering a percutaneous stent-graft to a patient, the method comprising:

a) inserting a first vascular access means into a first body lumen section of the patient;

10 b) inserting a second vascular access means into a second body lumen section of the patient;

c) providing an apparatus comprising a body implantable device comprising a self-expanding flexible tube of open weave construction having a first end and a second end, 15 the ends being compressible into a radially compressed state, the flexible tube having an elastic layer arranged along at least a portion of its length, first and second removable retaining elements secured to the flexible tube proximate the first and second ends, respectively, for maintaining the first 20 and second ends in radially compressed states, the retaining elements being adapted for insertion into the first and second vascular access means;

25 d) inserting the first and second removable retaining elements into the first and second vascular access means, respectively;

e) pushing the first and second removable retaining elements into the first and second vascular access means, respectively, until at least part of the flexible tube first end is disposed within the first body lumen and at least 30 part of the flexible tube second end is disposed within the second body lumen;

f) removing the first and second vascular access means; and

35 g) removing the first and second retaining means thereby allowing the first and second end sections to expand within the first and second body lumen sections, respectively.

19) The method of claim 18 further comprising the step of tunnelling between two incisions to create a percutaneous path for the stent-graft.

40 20) The method of claim 18 wherein the first and second

-17-

vessel segments comprise lumens having an internal surface and the body implantable device has at least one barb configured for engaging the internal surface of the first and second vessel segments.

1/9

FIG-1

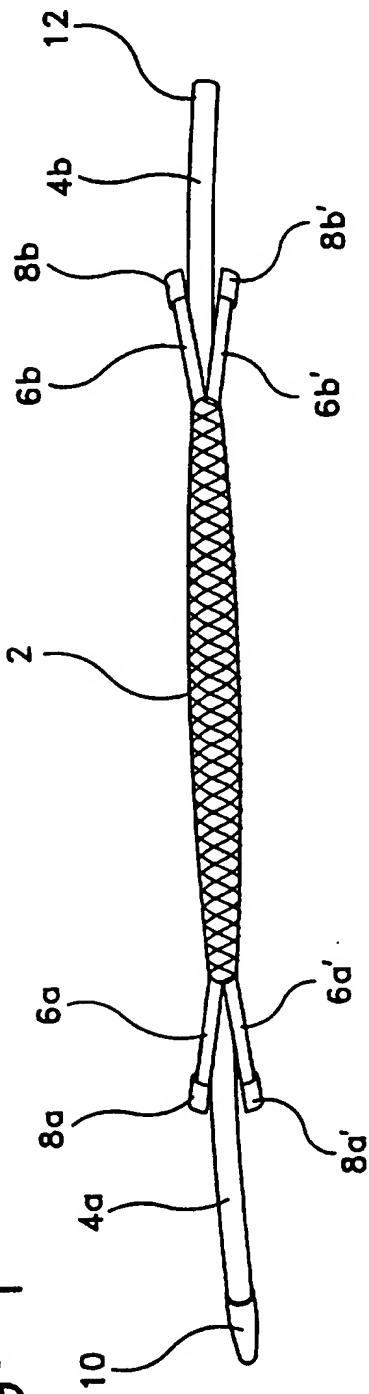


FIG-2

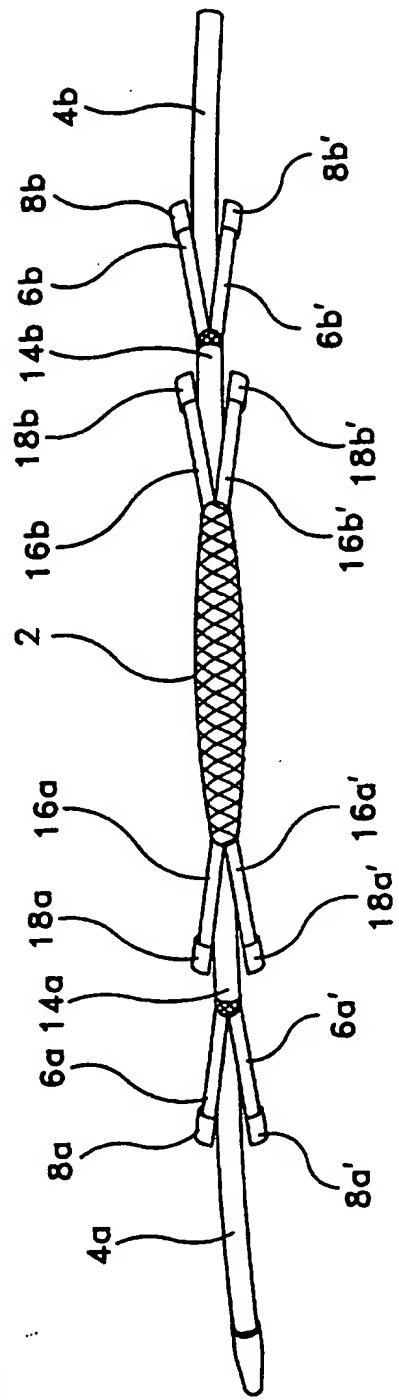
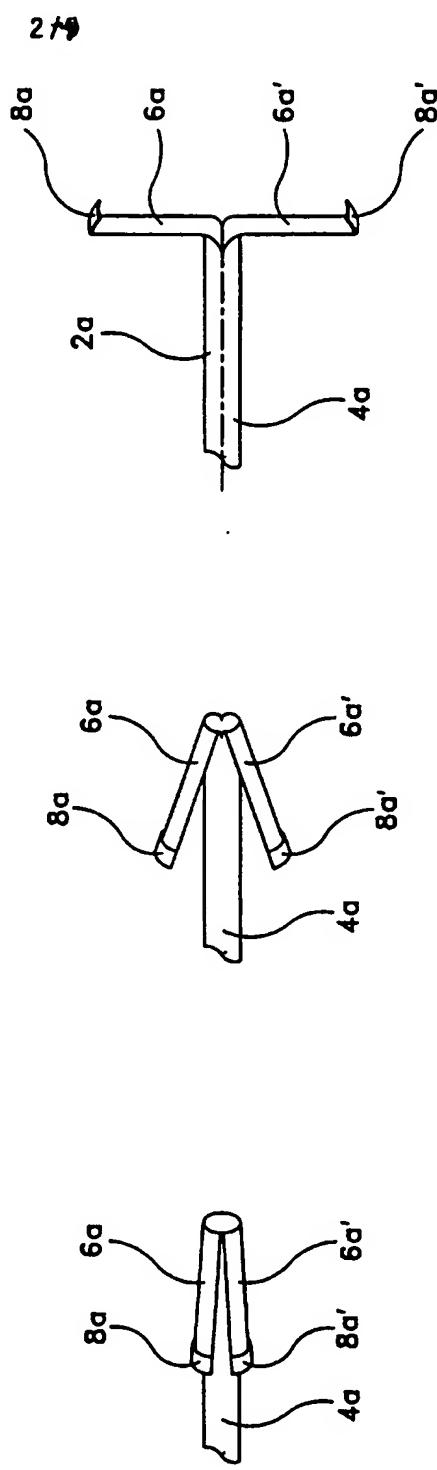


FIG-3a
FIG-3b
FIG-3c

3/9

FIG-4a

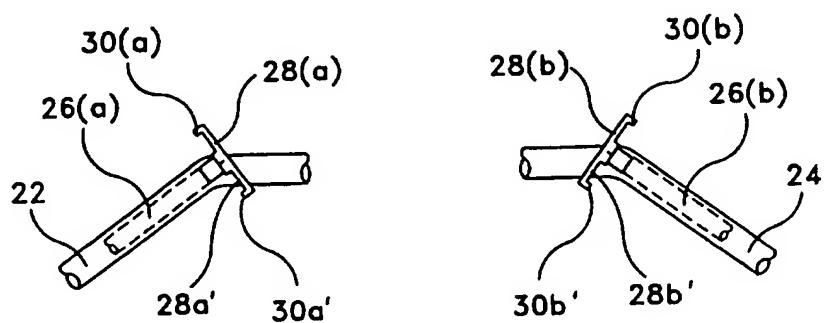


FIG-4b

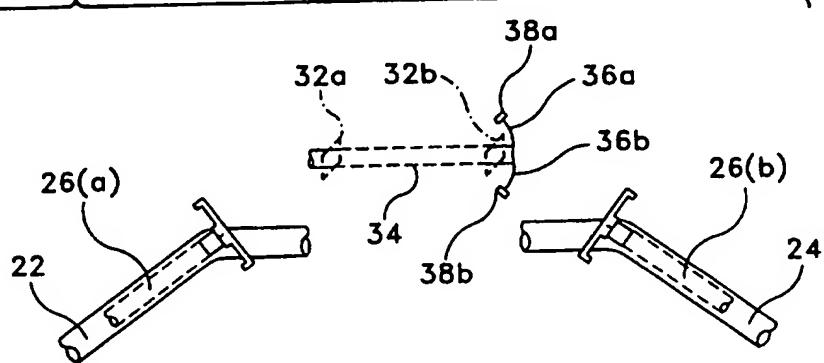
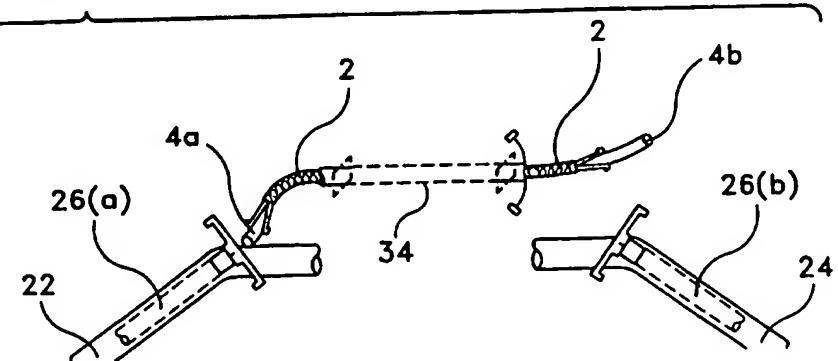


FIG-4c



4 / 9

FIG-4d

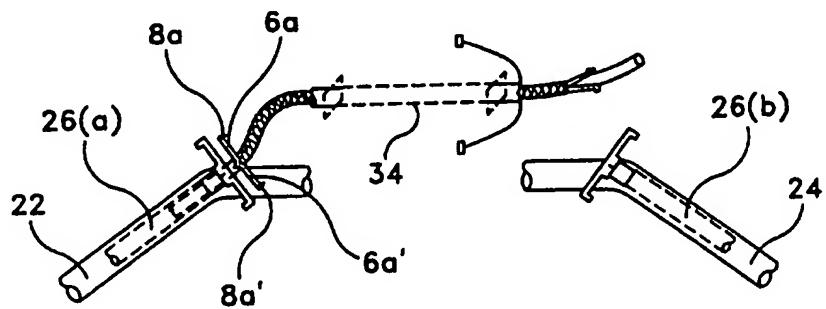


FIG-4e

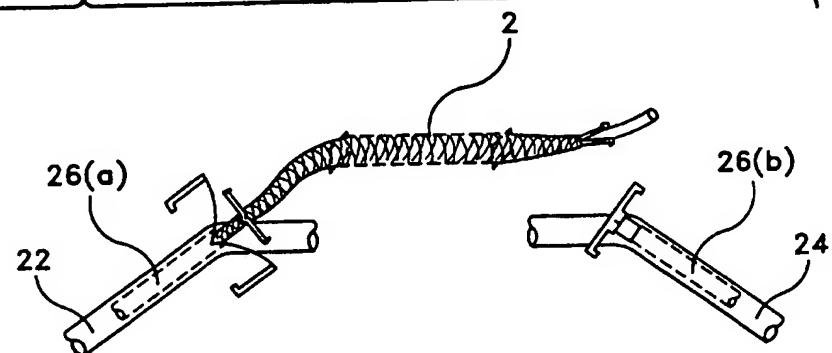
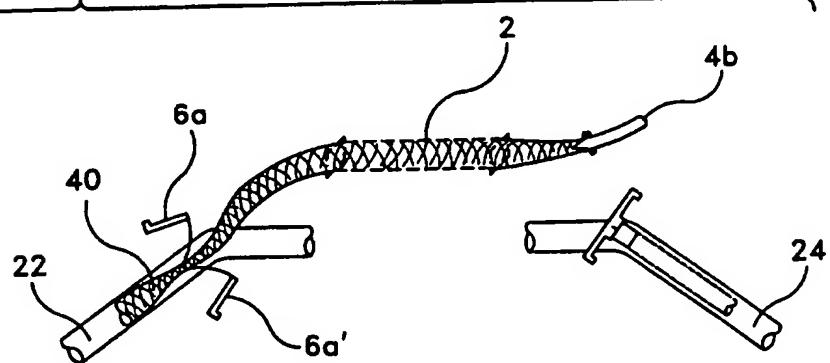


FIG-4f



5/9

FIG-4g

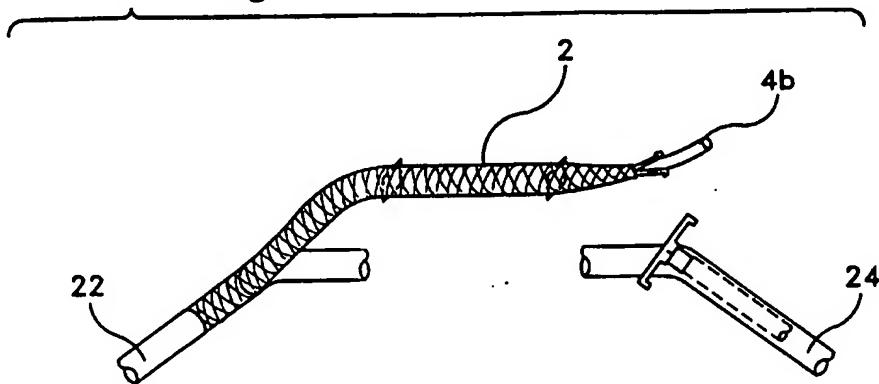


FIG-4h

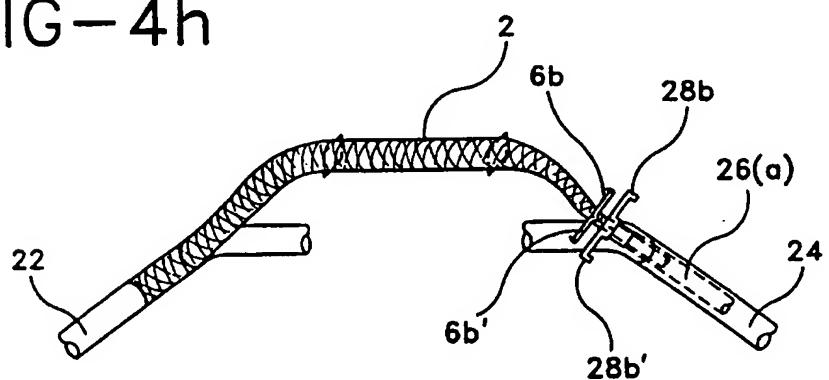
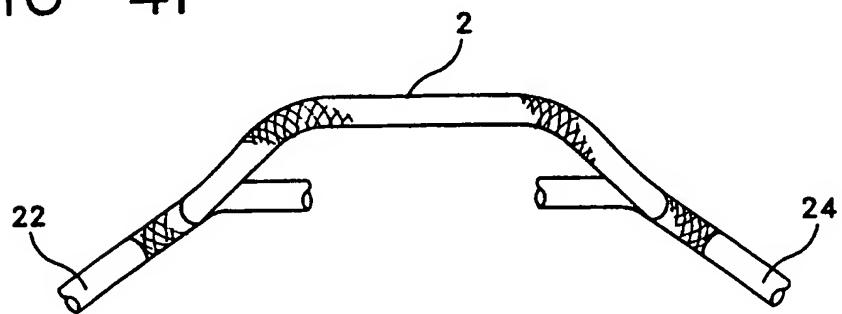


FIG-4i



6/9

FIG-5a

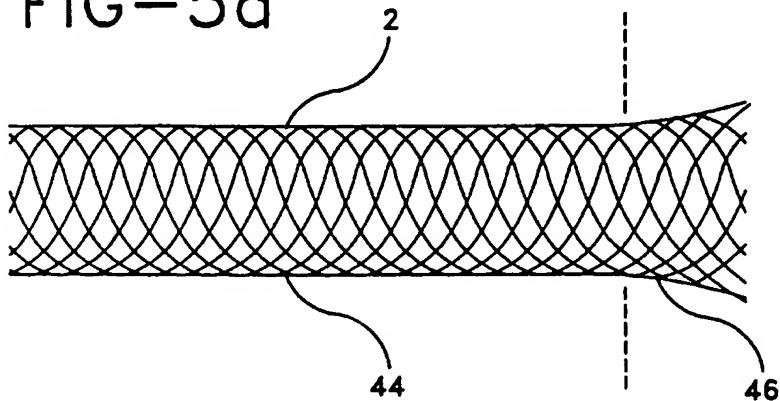


FIG-5b

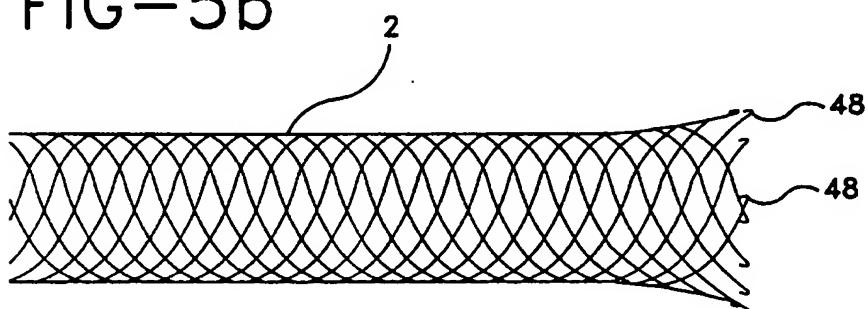


FIG-5c

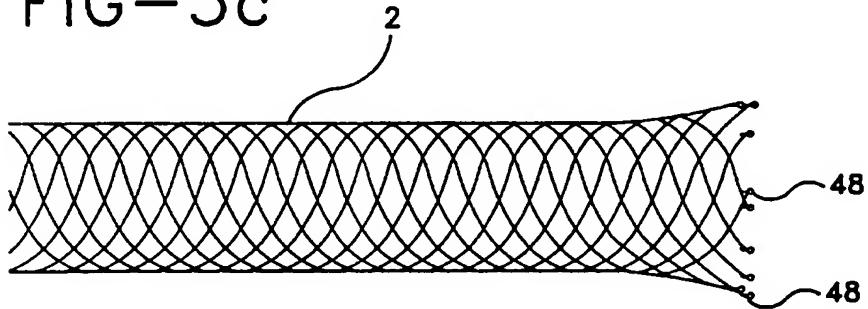


FIG-6

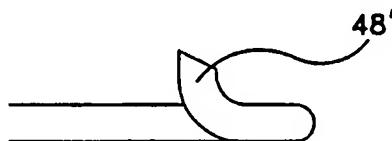


FIG-7a

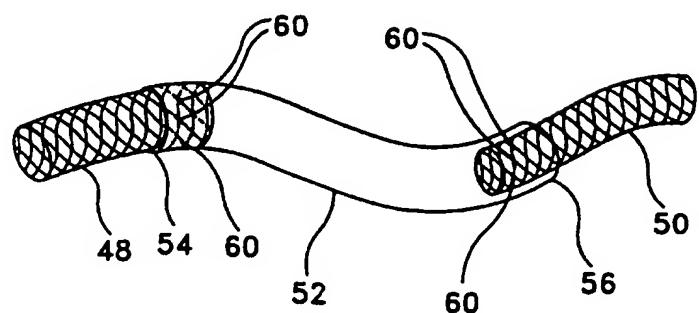


FIG-7b

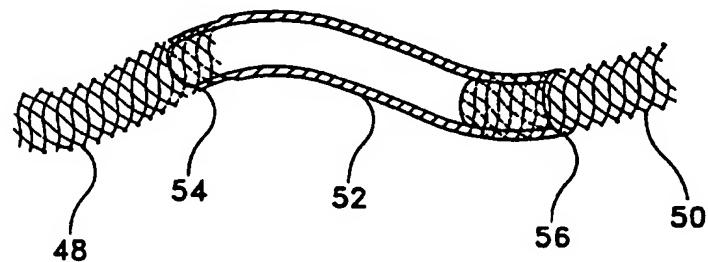


FIG-8

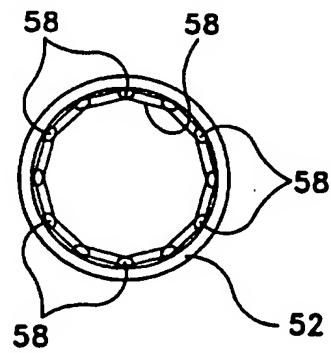


FIG-9a

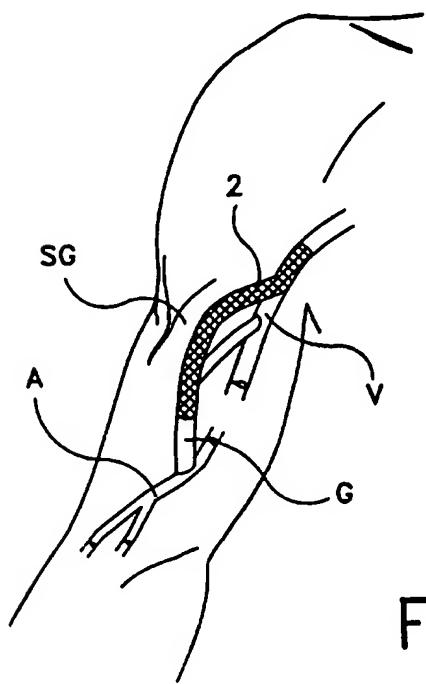


FIG-9b

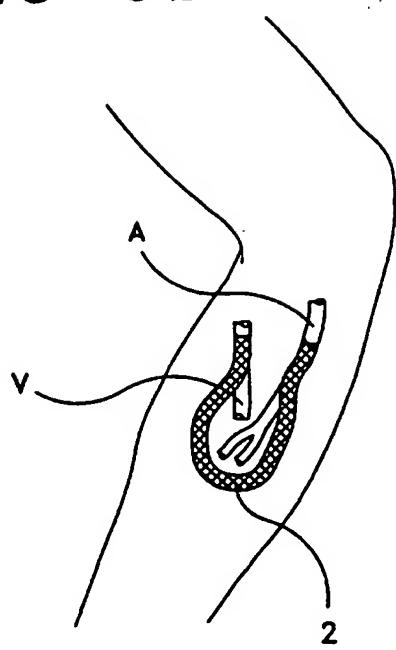
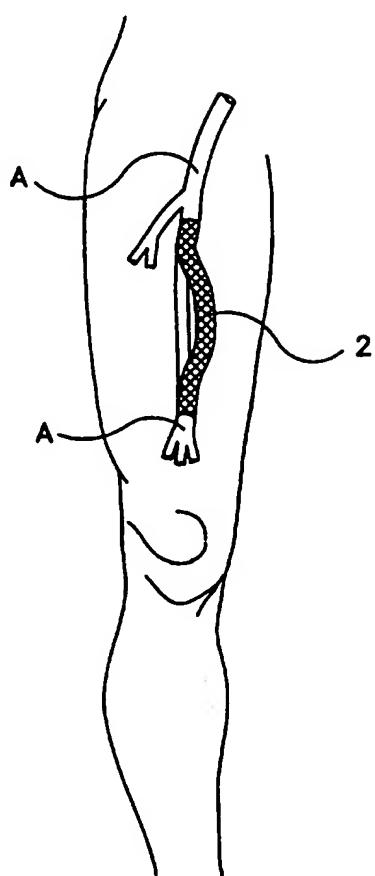


FIG-9c



INTERNATIONAL SEARCH REPORT

International application No.

PCT/US96/00397

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06

US CL :623/1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/96, 103, 104; 606/108, 191, 195, 198; 623/1, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P	WO, A, 95/14442 (VENBRUX) 01 June 1995, see entire document.	17-20
Y, P	US, A, 5,403,341 (SOLAR) 04 April 1995, see entire document.	1-16
Y	WO, A, 93/17636 (RICHARD) 16 September 1993, see entire document.	1-16
Y	US, A, 5,246,452 (SINNOTT) 21 September 1993, see entire document.	3, 4, 15, 16
Y	US, A, 4,804,382 (TURINA ET AL.) 14 February 1989, see entire document.	11

Further documents are listed in the continuation of Box C.

See patent family annex.

•	Special categories of cited documents:	
•A*	document defining the general state of the art which is not considered to be part of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
•E*	earlier document published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
•L*	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
•O*	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
•P*	document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

02 APRIL 1996

Date of mailing of the international search report

03 MAY 1996

Name and mailing address of the ISA/US
Commissioner of Patents and TrademarksBox PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MICHAEL MILANO

Telephone No. (703) 308-2496

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.